Exposure Driven Medical Surveillance Alternative

S. Smallets, CIH
NAVMEDCEN Portsmouth
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Medical Surveillance

- Purpose:
  - Protect workers who have significant exposure to hazardous chemicals or physical agents
    - Provide early indication of disease or body burden
  - Ideally would consider all routes of exposure
- Other Outcomes:
  - Ascertain effectiveness of PPE and administrative controls
  - Fulfills a regulatory requirement
- How are workers included in Medical Surveillance ?

Current Navy Policy

- Occupational Medicine Field Operations Manual NEHC 6260 TM96-2 page 5-2 states:
  - *"When there is no OSHA or Navy standard for a specific agent, individuals whose jobs are associated with exposures to hazards or stressors above the medical surveillance action level for more than 30 days per year or* 10 days per quarter *are placed into medical surveillance programs."*

Current Navy Policy

- Procedures Manual and Medical Matrix (Edition 7) NEHC-TM OM 6260 (February 2001) states:
  - *"Workers whose jobs are associated with exposures to hazards at or above the medical surveillance action level for more than 30 days per year or* 15 days per quarter *are placed into medical surveillance programs."*

Current Navy Policy

- Most OSHA 6.b rule standards (e.g. Lead, cadmium) require medical surveillance when the *Action Level is exceeded for > 30 days/year* .
  - Asbestos is the exception, as it has no regulatory action level (AL).
- AL typically defined as ½ of the Occupational Exposure Limit (OEL), HCHO, lead exception

Current Navy Policy

- Inclusion in medical surveillance is based on exceeding an Action Level (AL)

- AL decisions are based on a compliance sampling strategy, i.e.
  - sample highest risk employee
  - one day of required measurement.
  - The one day's measurement is used to draw conclusions regarding compliance on unmeasured days and is the sole basis for deciding whether further measurements should be made.

Issues-IH Sampling Strategy-Comprehensive

- OPNAVINST 5100.23 requires a comprehensive sampling strategy for exposure assessment e.g. AIHA
  - Establish similar exposure groups (SEGS)
  - Define an exposure profile, e.g. 6-10 measurements to accurately describe exposures.
    - Profile is an estimate of the exposure magnitude and variability.
  - Judge profile as acceptable, unacceptable
  - Decisions regarding workplace based on profile

Issues-IH Sampling Strategy

- We have two distinct approaches for IH decision making
  - Medical surveillance - AL- compliance
  - Everything else – comprehensive

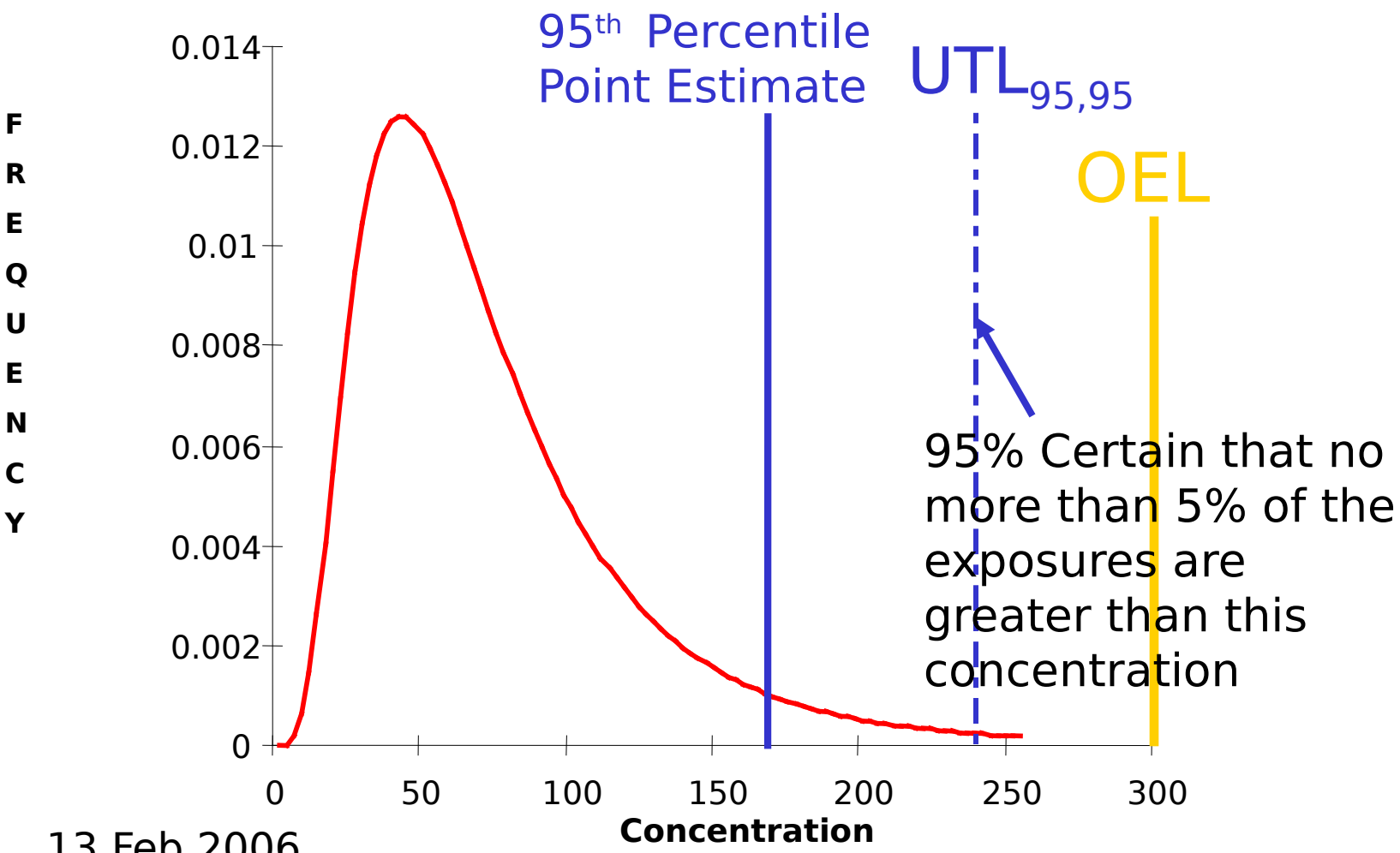
Issues-IH Sampling Strategy

- If the Navy were to go with the comprehensive approach for Medical surveillance
  - Is the comprehensive strategy as protective as the compliance approach ?
  - What point estimate would be the best - 95th percentile or UTL 95,95?
  - What are the differences in outcomes between the comprehensive and compliance approach?
  - What would be the impact ?

Policy - Basis

- "Exposure Measurement Action Level and Occupational Environmental Variability", NIOSH Pub 76-131 and "Occupational Exposure Sampling Strategy Manual", NIOSH Pub 77-173 provide the basis for the action level concept.
  - The action level was set with the view that the employer should minimize the probability that even a very low percentage of actual daily employee exposure averages will exceed the standard. P 118
  - In statistical terms, the employer should try to attain 95% confidence that no more than 5% of employee days are over the standard. P 118

95th percentile and UTL 95%,95%



Test Methods-Compare Comprehensive v.s. Compliance

- Computer simulation
  - Adapted a spread sheet routine created by Dr. Paul Hewett
- Created 30 populations
  - GSD 1.5, 2.0, 2.5, 3.0, 3.5 with P (c>OEL) of 0.001, 0.01, 0.05, 0.1, 0.2, 0.4
  - Populations with P (c>OEL) of 0.001 and 0.01 considered acceptable i.e. no medical surveillance needed
  - Populations with P (c>OEL) of 0.05, 0.1, 0.2 and 0.4 would require medical surveillance

Test Methods

- For 95th percentile and UTL 95,95 (Comprehensive)
  - 5000 iterations of 10 sam
  - For each group of 10
    - Calculated 95%ile and UTL 9
    - Counted number of times 9
    - # times OEL exceeded/5000 expressed as a percentage
- For AL (Compliance)
  - 5000 iterations of 1 sample
    - Counted number > ½ OEL
    - # times OEL exceeded/5000 expressed as a percentage

95th percentile = exp(GM +(1.645*std))

UTL 95, 95 = exp(GM +(2.911*std))

0.1 %
P(c>OEL)=0.001

P(c>L)	GSD	1.5	2.0	2.5	3.0	3.5
0.001	Compliance					
	AL	9	2	1	1	1
	Comprehensive					
	95%tile	0	0	0	0	0
	95%UTL	28	29	30	29	28

-0.1% exceedance is considered acceptable

-At 1.5 GSD AL strategy would include 9% 95th %tile 0%

-At higher GSDs AL and 95th%tile similar

-95% UTL small sample sizes includes ~29%

1 %
P(c>OEL)=0.01

P(c>L)	GSD	1.5	2.0	2.5	3.0	3.5
0.01	Compliance					
	AL	27	9	6	5	4
	Comprehensive					
	95%tile	5	5	5	5	5
	95%UTL	69	69	71	69	70

-1% exceedance would generally be considered acceptable

-At 1.5 GSD AL strategy would include 27%

-At higher GSDs AL and 95th%tile similar

-95%UTL small sample sizes includes ~70%

5 % P(c>OEL)=0.05

p(c>L)	GSD	1.5	2.0	2.5	3.0	3.5
0.05	Compliance					
	AL	**53**	26	18	15	15
	Comprehensive					
	95%tile	**40**	40	41	40	40
	95%UTL	94	94	94	93	94

-5% exceedance is considered unacceptable

-At 1.5 GSD AL strategy would include 53% 95th%tile 40%

-At higher GSDs AL is less protective

-95%UTL includes 94% best indicator

10% P(c>OEL)=0.1

P(c>L)	GSD	1.5	2.0	2.5	3.0	3.5
0.1	Compliance					
	AL	**67**	40	30	27	23
	Comprehensive					
	95%tile	**70**	69	70	69	69
	95%UTL	98	98	98	98	98

-10% exceedance is considered unacceptable

-At 1.5 GSD AL strategy would include 67% 95th%tile 70%

-At higher GSDs AL is less protective

-95%UTL includes 98% best indicator

20% P(c>OEL)=0.2

P(c>L)	GSD	1.5	2.0	2.5	3.0	3.5
0.2	Compliance					
	AL	82	57	47	43	38
	Comprehensive					
	95%tile	93	93	93	92	93
	95%UTL	100	100	100	100	100

-20% exceedance is considered unacceptable

-At 1.5 GSD AL strategy would include 82% 95th%tile 93%

-At higher GSDs AL is less protective

-95%UTL includes 100% best indicator

40% P(c>OEL)=0.4

P(c>L)	GSD	1.5	2.0	2.5	3.0	3.5
0.4	Compliance					
	AL	92	76	69	65	62
	Comprehensive					
	95%tile	100	100	100	100	100
	95%UTL	100	100	100	100	100

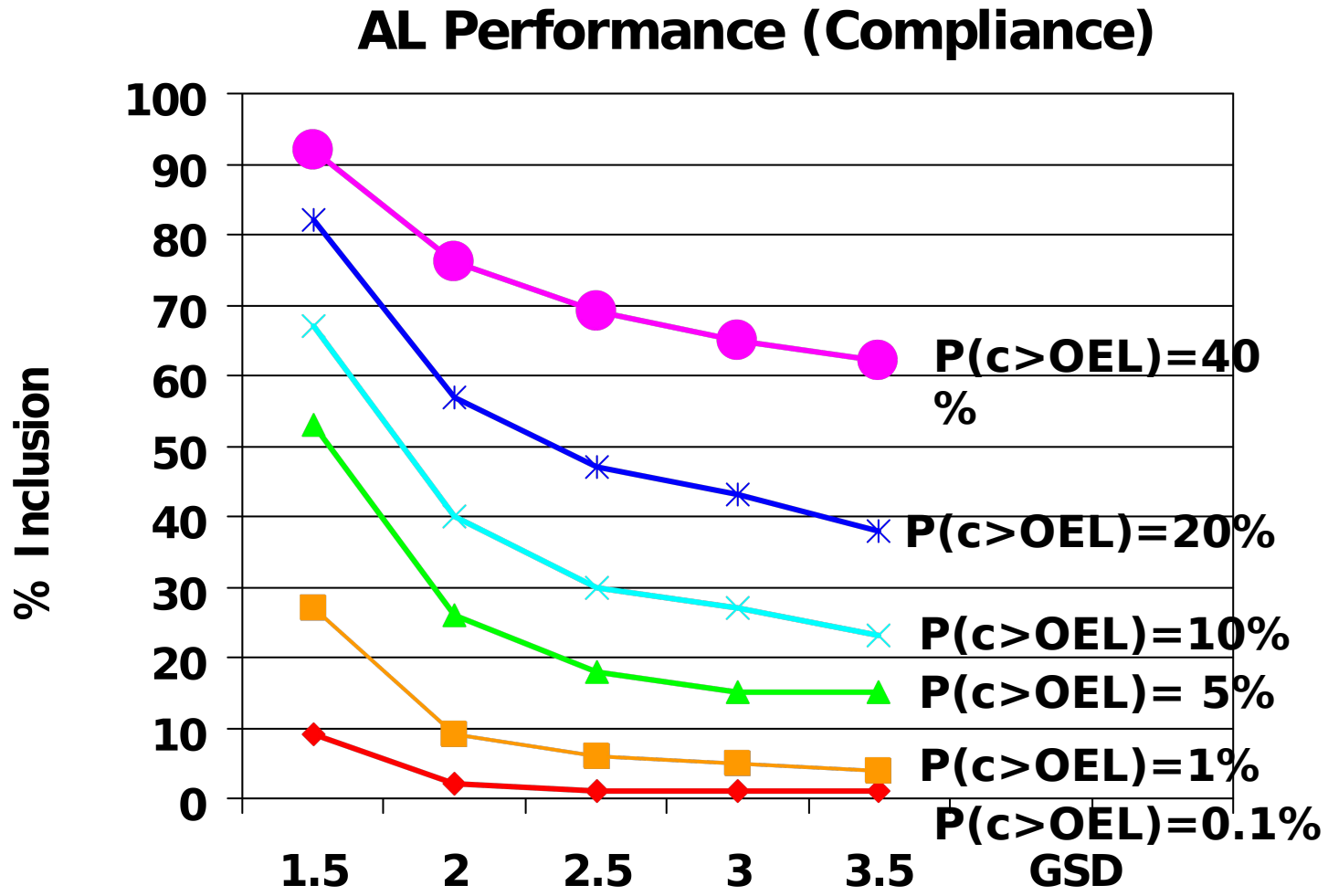
-40% exceedance is considered unacceptable

-At 1.5 GSD AL strategy would include 92% 95th%tile 100%

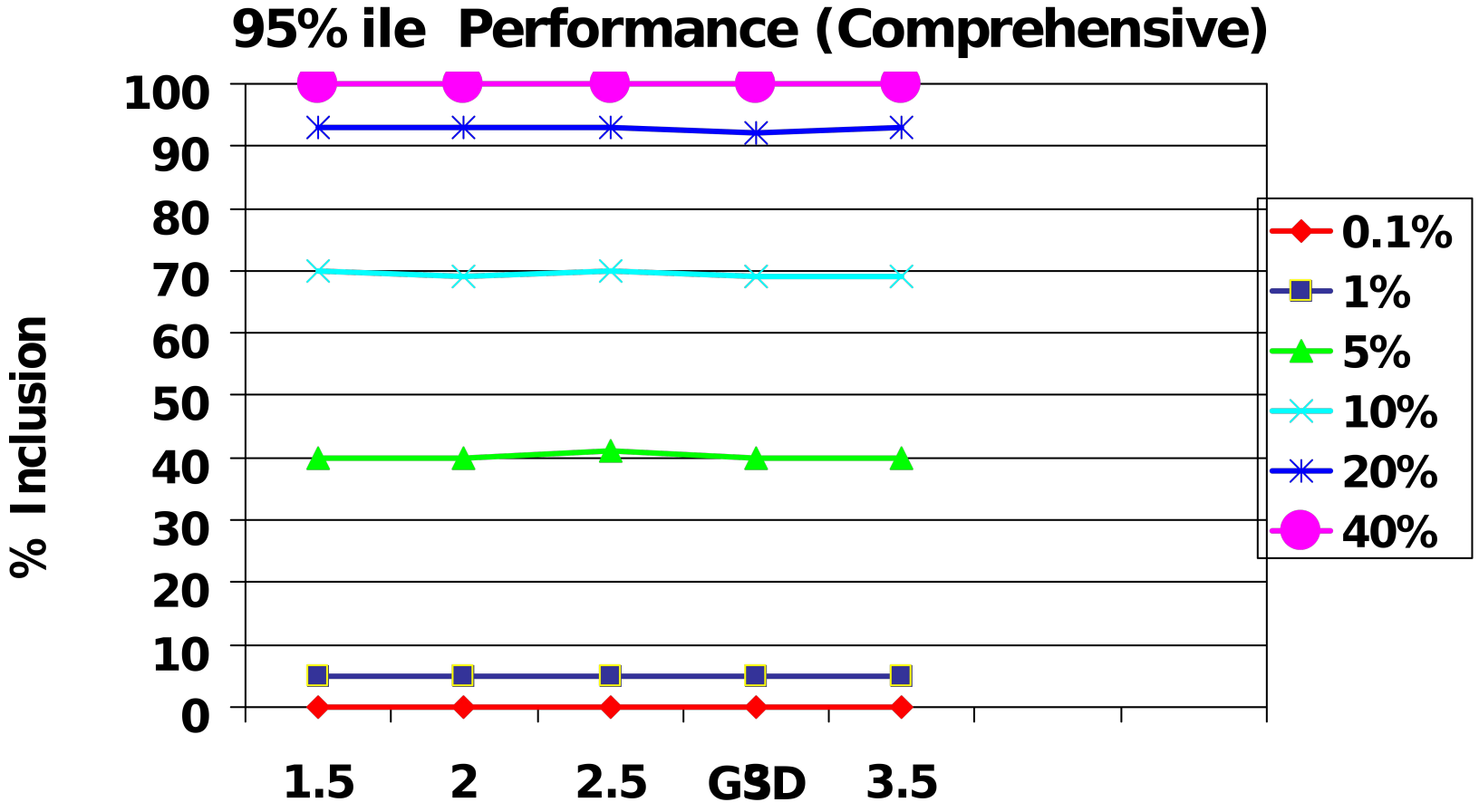
-At higher GSDs AL is less protective

-No difference between 95%UTL and 95th%tile

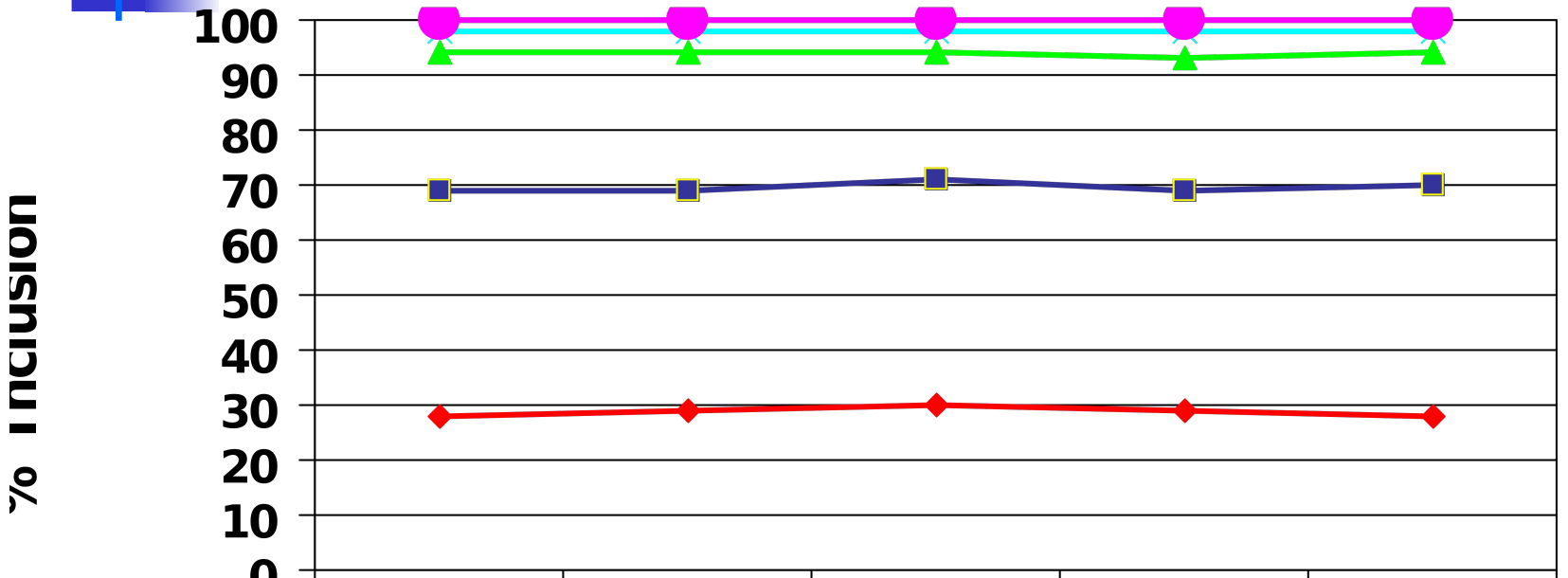
AL Performance Curves



95th Percentile Performance



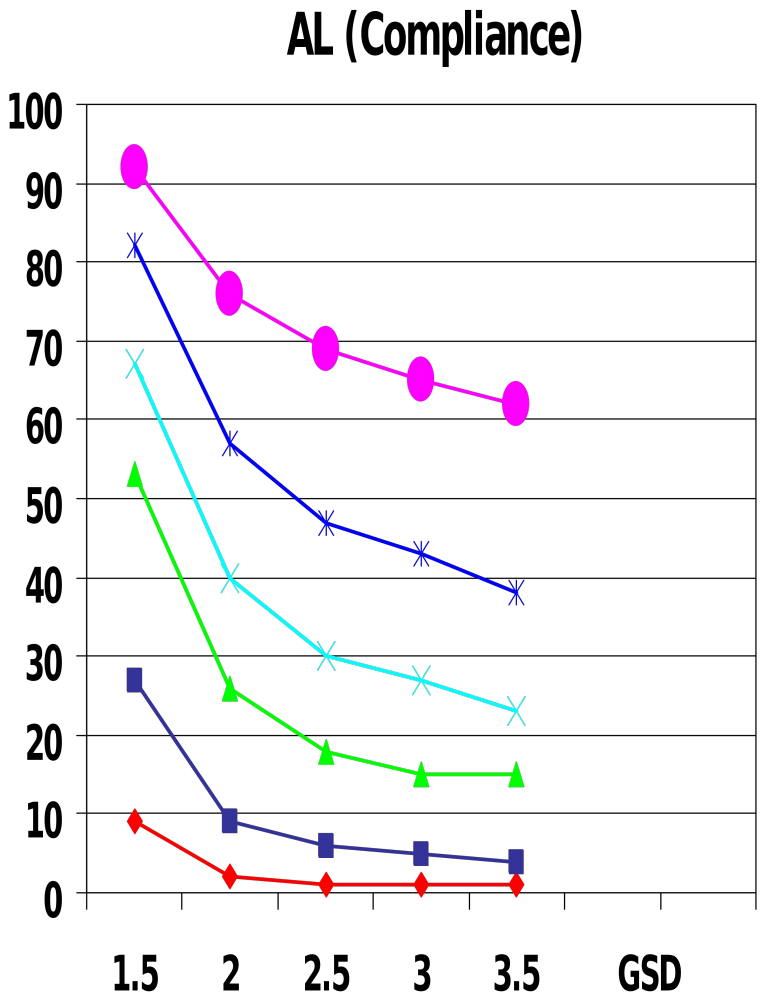
95% UTL Performance

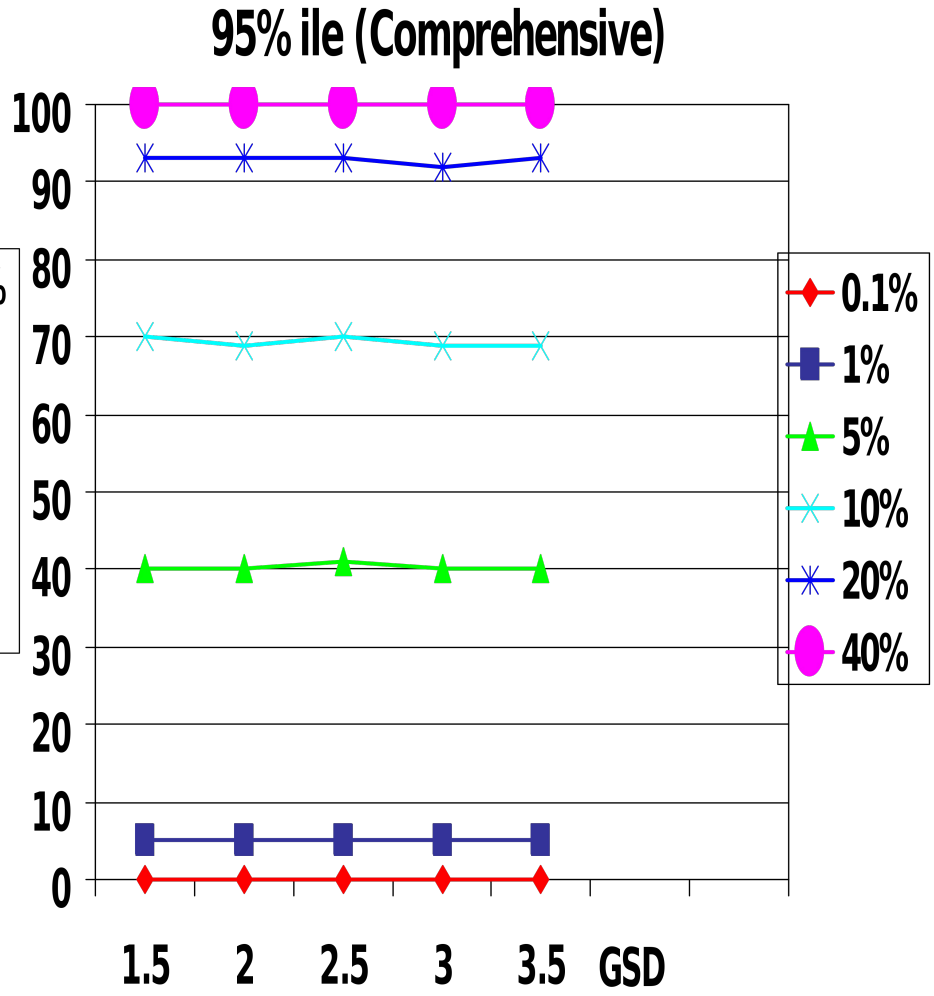


	1.5	2	2.5	3	3.5
0.1%	28	29	30	29	28
1%	69	69	71	69	70
5%	94	94	94	93	94
10%	98	98	98	98	98
20%	100	100	100	100	100
40%	100	100	100	100	100

GSD

Comparison of AL and 95th





Conclusions

- Is the comprehensive strategy as protective as the compliance approach ?
  - As protective except in the case where GSD is very low i.e. GSD 1.5 P(c>OEL)=0.05.
  - In other instances more protective
- What point estimate would be the best - 95th percentile or UTL 95,95?
  - For a sample size of 6-10
  - 95th percentile is the best choice
  - UTL 95,95 includes a large percentage when exposures are low (most conservative)
    - Does provide information about certainty of assessment

Conclusions

- What are the differences in outcomes between the comprehensive and compliance approach?
  - Comprehensive approach much better at detecting high exposures across a range of GSD's
  - Compliance approach detects less as GSD increases
- What would be the impact ?
  - Depends on how closely the current compliance model is followed

Recommendations/ Suggestions

- BUMED consider promoting a consistent sampling strategy for all IH decision making
- BUMED consider incorporating a comprehensive sampling strategy for hazard based medical surveillance decisions into Navy policy.
  - Use the 95th percentile as decision point
- Use of SME to validate

Recommendations-IH Sampling Strategy

Exposure Rating	***Quantitative Exposure Assessment***	***Recommend Placement into Medical Surveillance***
3	95th Percentile exceeds OEL	Yes **Days/Year**
2	95th Percentile below OEL & UTL > OEL	No
1	95th Percentile below OEL & UTL < OEL	No